UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,995	06/20/2006	Robert Francis Grimble	BJS-620-397	6576

23117 7590 01/30/2009

NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER	
STRZELECKA, TERESA E	
ART UNIT	PAPER NUMBER
1637	

MAIL DATE	DELIVERY MODE
01/30/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,995	GRIMBLE ET AL.	
	Examiner	Art Unit	
	TERESA E. STRZELECKA	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2008*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *11-19* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. This office action is in response to an amendment filed November 13, 2008. Claims 1-10 were previously pending. Applicants cancelled claims 1-10 and added new claims 11-19.

2. Applicants' claim cancellation overcame all of the previously presented claim rejections.

3. Applicants' submission of a letter stating that the CRF and paper copies of the sequence listing are the same obviated the previously presented objection.

4. The newly added claims require restriction for reasons given below.

5. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 11, drawn to a method for assessing the sensitivity of an individual to the anti-inflammatory effects of fish oil comprising determining the genotype of the LT-α +252 allele and predicting a sensitivity of the individual to the anti-inflammatory effects of fish oil when the individual is homozygous for the TNFB2 allele.

Group II, claim(s) 12, drawn to A method for assessing the sensitivity of an individual to the anti-inflammatory effects of fish oil comprising:

determining the inherent TNF- α production of the individual;
determining the genotype of the LT- α +252 allele; and
predicting a greater sensitivity of the individual to the anti-inflammatory effects of fish oil when the individual is heterozygous for the LT- α +252 allele and has low or medium levels of inherent TNF- α production than when the individual is heterozygous for the LT-α +252 allele and has high levels of inherent TNF- α production.

Group III, claim(s) 13, drawn to a method for assessing the sensitivity of an individual to the anti-inflammatory effects of fish oil comprising determining the genotype of the IL-6 -174 allele and predicting a higher sensitivity of the individual to the anti-inflammatory effects of fish oil when

the individual has the IL-6 -174 CC genotype than when the individual is has the IL-6 -174 GG or IL-6 -174 GC genotype.

Group IV, claim(s) 14, drawn to a method for assessing the sensitivity of an individual to the anti-inflammatory effects of fish oil comprising:

determining the genotype of the IL-6 -174 allele;

determining the genotype of the LT-α +252 allele; and

predicting a higher sensitivity of the individual to the anti-inflammatory effects of fish oil when the individual has the IL-6 -174 GG and TNFB 1/2 genotypes than when the individual has other genotypes of these alleles.

Group V, claim(s) 15-19, drawn to a method of reducing TNF-α production in an individual, comprising
a) determining the genotype of at least one of the LT-α +252 allele and the IL-6 - 174 allele; and
b) administering to said individual a therapeutically effective amount of fish oil based on the genotype of the individual.

6. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Grimble et al. (Am. J. Clin. Nutr., vol. 76, pp. 454-9, August 2002; cited in the IDS) teach a method of claim 11 (Abstract; page 455, third and fifth paragraph; page 456, last paragraph; page 457, first and second paragraphs; Table 4 and 5). Therefore, the claims do not represent a contribution over prior art and thus lack a unifying special technical feature.

7. This application contains claims directed to more than one species of the generic invention.

These species are deemed to lack unity of invention because they are not so linked as to form a

single general inventive concept under PCT Rule 13.1.

The species are as follows:

Group V

Species of a disorder

A) atopic dermatitis (claim 17, 18),

B) contact dermatitis (claim 17, 18),

C) eczema (claim 17, 18),

D) psoriasis (claim 17, 18),

E) Perianal Crohn's disease (claim 17),

F) rheumatoid arthritis (claim 17, 19),

G) psoriatic arthritis (claim 17, 19).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 15, 17.

8. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the species are diseases which have different etiologies and symptoms.

9. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and

specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TERESA E. STRZELECKA whose telephone number is (571)272-0789. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Teresa E Strzelecka
Primary Examiner
Art Unit 1637

/Teresa E Strzelecka/
Primary Examiner, Art Unit 1637
January 27, 2009